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| EXAMINER | |
|---|---|
| HUGHES, ALICIA R | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

| NOTIFICATION DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/590,031 | DOLFI ET AL. | |
| | Examiner | Art Unit | |
| | ALICIA R. HUGHES | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

Claims 13-30 are pending and the subject of this Office Action.

### *Priority Assigned to Claims*

Applicants claim priority for this Application dating back to 17 February 2005, the date of filing for PCT/FR05/00370. Upon review of the disclosures contained therein, the Office concludes that to assign 17 February 2005 priority to claims 13-30 in the instant application is proper for prior art for 35 U.S.C. §102(b) considerations herein.

### *Claim Rejection - 35 U.S.C. §112.2*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-30 are rejected under 35 U.S.C. §112, second paragraph for indefiniteness. Claims 13-30, as written, are vague and indefinite, because the claims include reference to "IL-8RB" and PAC-1" but does not disclose to what IL or PAC refers. When Applicants make a claim which references a particular for the first time in a claim set, Applicants should write out the full name of the particular to which he refers and accompany that full name with the abbreviation in brackets, if desirous of using an abbreviation of same thereafter.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent Application No. 10/590074. Although the conflicting claims are not identical, they are not patentably distinct from each other, because they contain identical subject matter and

both relate to a pharmaceutical composition comprising an effective amount of metronidazole to treat rosacea.

These are provisional nonstatutory obviousness-type double patenting rejection, because the claims have not, in fact, been patented.

### *Claim Construction*

For the purpose of examination herein, claims are assigned their broadest reasonable interpretation. As such, "IL-8RB" is construed to mean interleukin-8RB. Further, about is construed to encompass, in terms of composition weights, a range of numbers lower and higher than those disclosed in the claims explicitly, in addition to all numbers falling between a specified range.

### *Claim Rejections – 35 U.S.C. §103(a)*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-30 are rejected under 35 U.S.C. §103(a), because they are obvious in view of by U.S. Patent Pre-Grant Publication No. 2002/0183399 [hereinafter referred to as "Kang et al"].

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Kang et al disclose that metronidazole and as well, the antibiotics tetracycline, doxycycline, minocycline, ampicillin and erythromycin are effective active ingredients in compositions utilized to treat rosacea (Para. 9, lines 6-22; see also para. 35, generally). Kang et al also teach that metronidazole, which is classified as an antiprotozoal, is available commercially as a 0.75% gel for topical application (Para. 9, lines 24-27).

Kang et al also teach that the typical course of treatment for rosacea is to start with metronidazole and where this treatment alone is not optimally effective, to follow up with the administration of an antimicrobial/antibiotic, such as minocycline or tetracycline to reduce inflammation (Para. 10, lines 1-11). As early as 1990, it was well-understood in the art that the combination of metronidazole combined with palmitoleic acid had a synergistic effect on inhibiting free radical generation by human neutrophils, including the generation reactive oxygen species, and on inhibiting the anaerobic growth of *P. acnes* (Paragraph 11 in total).

The composition in Kang et al contemplates the use of retinoids as useful treatment of rosacea also (Para. 41, in total), including each of its varied "stages." The composition also contemplates, in addition, one or more cosmetically compatible, acceptable adjuvants commonly used, such as colorants, fragrances, humectants and the like (Paragraph 38 in total). The composition can be, when used topically, in

concentrations between about 0.05% and about 5% (Paragraph 39 in total) and can come in the form of lotions or creams or ointments, for example, as well as in spray form (Paragraph 37 in total).

It is well-understood in the art that intended use does not limit use, and that as a matter of law, once a reference teaching a product that appears to be substantially identical is made the basis of a rejection and the Examiner has presented evidence or reasoning tending to show inherency, the burden shifts to the Applicant to show that there is an unobvious difference. Moreover, "[t]he PTO can require an applicant to prove that the prior art products do not necessarily possess the characteristics of his [or her] claimed product … Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on '*prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." *In re Fitgerald, et al.*, 205 USPQ 594 (CCPA 1980) *quoting In re Brown*, 173 USPQ 685, 688 (CCPA1972).

In the instant case, the intended use of metronidazole for treating cutaneous inflammation does not preclude use of the same from modifying the secretion of various interleukins or from treating varied stages of rosacea, psoriasis, acute inflammation, chronic inflammation, septic shock, and/or autoimmune disease as it necessarily follows that all, in absence of express evidence to the contrary, come about as a result of inherent properties existent in metronidazole.

In light of the foregoing, the instant invention is prima facie obvious in view of the prior art cited.

## Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614